

Triclosan-coated sutures reduce the incidence of wound infections and the costs after colorectal surgery: A randomized controlled trial

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Background. In colorectal surgeries, surgical site infections (SSIs) frequently cause morbidity; an incidence of up to 20% has been shown in previous studies. Recently, to prevent microbial colonization of suture material in operative wounds, triclosan-coated polyglactin suture materials with antimicrobial activity have been developed; however, their significance in colorectal surgery remains unclear. This randomized controlled trial was conducted to assess the value of triclosan-coated polyglactin sutures in colorectal surgery.

Methods. A total of 410 consecutive patients who had undergone elective colorectal operations were enrolled in this trial. Of those patients, the 206 in the study group underwent wound closure with triclosan-coated polyglactin 910 antimicrobial sutures, and the 204 patients in the control group received conventional wound closures with polyglactin 910 sutures.

Results. The study group and the control group were comparable regarding risk factors for SSIs. The incidence of wound infection in the study group was 9 of 206 patients (4.3%), and that in the control group was 19 of 204 patients (9.3%). The difference is statistically significant in the 2 groups ($P = .047$). The median additional cost of wound infection management was \$2,310. The actual entire additional cost, therefore, of 9 patients in the study group was \$18,370, and that of 19 patients in the control group was \$60,814.

Conclusion. Triclosan-coated sutures can reduce the incidence of wound infections and the costs in colorectal surgery. (*Surgery* 2013;153:576-83.)

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SURGICAL SITE INFECTIONS (SSIs) account for the most common cause of nosocomial infections in surgical patients, increase medical costs, and prolong hospital stays.¹⁻⁴ In colorectal surgery, SSIs frequently cause morbidity, with an incidence of up to 20%, as indicated by previous studies.⁵⁻⁷ One of the reasons for the development of wound infections that has been reported in the surgical literature for many years is microbial adherence to the surface of suture material.^{8,9} Recently, to prevent microbial colonization of suture material in operative wounds, triclosan-coated polyglactin sutures with antimicrobial activity have been

developed.¹⁰⁻¹³ Several clinical studies have demonstrated that the use of triclosan-coated polyglactin sutures leads to reduction of wound infections after various surgeries.¹⁴⁻²² Only 2 randomized controlled trials with a small number of colorectal patients, however, have been performed; the significance of the triclosan-coated polyglactin sutures in colorectal surgery, therefore, remains unclear.

The purpose of this study was to evaluate whether the incidence of wound infections can be reduced when triclosan-coated sutures are used for abdominal wound closures and to evaluate the impact on the costs associated with wound infections after colorectal surgery.

METHODS

Patients. A total of 415 patients who underwent elective colorectal operations in the Department of Surgery of Teine-Keijinkai Hospital (a 550-bed private hospital that performs 7,500 surgeries annually) in Sapporo, Japan, between April 2009 and March 2011, registered, and 410 enrolled in this

Accepted for publication November 16, 2012.

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0039-6060/\$ - see front matter

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<http://dx.doi.org/10.1016/j.surg.2012.11.018>

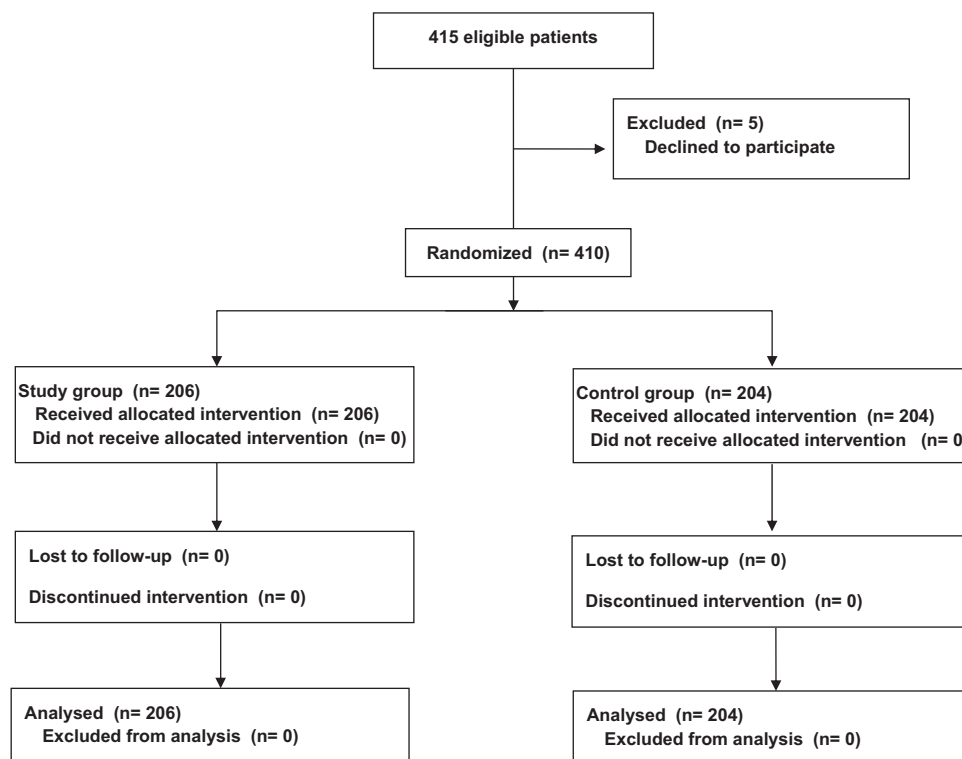


Fig. Study flow diagram. We excluded 5 patients from this trial before randomization, as indicated in the text.

study. We excluded 5 patients from the study before randomization because of the absence of informed consent (Fig). We studied 206 patients who had undergone wound closure with triclosan-coated polyglactin 910 antimicrobial sutures (Vicryl* Plus; Ethicon, Somerville, NJ) and 204 patients who had conventional wound closures with polyglactin 910 sutures (Vicryl*) in the control group. Patients were randomly assigned by the envelope method into the 2 groups, and data were collected prospectively. Informed consent for participation was obtained from each patient before enrollment in the study, which was approved and registered by the Human Research Review Committee of the Teine Keijinkai Hospital (Infrastructure for Academic Activities University Hospital Medical Information Network Identifier: UMIN000003322, www.umim.ac.jp/ctr/index/htm/). This institution's wound infection rate for elective colorectal surgery was about 10% to 11% in 2007 and 2008 (data not shown); thus, the assumed expected wound infection rates of 4% to 5% for the study group and 10% to 11% for the control group. With a 2-sided $\alpha = 0.05$, the study was expected to have 80% power to detect a relative risk reduction of 5%; a total of 400 patients were estimated to be needed. The G*Power

3 software (Heinrich-Heine University, Düsseldorf, Germany) was used to calculate the sample size.²³

All patients received intravenous antibiotic prophylaxis, a cephalosporin, 30 min before incision; every 3 h of operative time; and after operative time, for 48 h in both groups. Wound protectors were used during open surgery, and lap protectors were used during delivery of specimens during laparoscopic surgery. Wound closure was achieved by the technique of interrupted sutures and surgical staples for skin by 7 trained surgeons. All surgeons at this institution usually use interrupted sutures for all abdominal closures; the same method, therefore, was used in this study. Although interrupted sutures increase the incidence of incisional hernia, the incidence of SSIs remains controversial.^{24,25} Considering the focus on SSIs in this study, therefore, interrupted sutures exert a small influence in the study design. Wound infection was identified according to the Centers for Disease Control and Prevention criteria (CDC) guidelines of 1999.¹ After the surgery, patients were followed-up daily during their hospital stays by a trained physician, and after discharge patients were monitored in the outpatient clinic weekly up to 30 days. None of the surgeons was blinded to the closure method used with either conventional

sutures or triclosan-coated sutures. The 7 trained physicians were, however, blinded to the assessment of the wound infections at the bedside, according to the CDC guidelines. No neoadjuvant chemotherapy was done in any of the patients in this study, and none of the patients having abdominoperineal resections received radiotherapy.

Using the fee-for-service calculation method (the standardized national Japanese set costs of health care) based on the medical fee table of the fiscal years 2008 and 2010, medical costs were calculated by aggregating the medical costs generated during the additional treatment period of wound infections. Medical costs were converted into US dollars at the exchange rate of ¥1 = US \$0.0125 during the study period.

The primary outcome of this study consists of the number of wound infections, and the secondary outcome consists of the extra cost owing to the care for infected wound management.

Statistical analysis. Differences between the 2 groups were calculated by the Student *t* test or the Mann-Whitney U test using SPSS (Version 14, IBM, Chicago, IL) software. The significance level was set at $P = .05$. Standard deviations are shown for the mean values. This institution's wound infection rate in elective colorectal surgery is about 10% to 11% in 2007 and 2008 (data not shown). The assumed wound infection rates were expected to be 5% for the study group and 10% for control group. With a 2-sided $\alpha = 0.05$, the study was expected to have 80% power to detect a relative-risk reduction of 5%.

RESULTS

Comparison of patient demographics, perioperative status. The patient demographics in both groups, as well as surgical site infection risk factors, are shown in Table I. No statistically significant difference existed between the 2 groups. In diabetic patients, a glycemic control protocol was not used in this study. The perioperative data of both groups are shown in Table II, and there was no statistically significant difference between them.

Incidence of wound infections and postoperative hospital stay. The incidence of wound infection in the study group was 9 of 206 patients (4.3%) and that in the control group was 19 of 204 patients (9.3%), thereby rendering a statistically significant difference between the groups ($P = .047$) (Table III). No statistically significant difference in the incidence of organ-space SSIs and length of postoperative hospital stay exists between the 2 groups. Table IV compares the wound infection rate in the laparoscopic approach (LAP),

5.3% vs the open approach, 8.7% ($P = .16$). The LAP was not independently associated with reduced SSIs when compared with the open approach; however, within each group, the control group in open surgery had a higher wound infection rate, 12.3% (Table V).

Cost of wound infection. During the study, wound infection developed in 28 patients. The median additional cost of wound-infection management in the inpatient and outpatient settings was \$2,310. The actual entire cost, therefore, of 9 patients in the study group was \$18,370 (theoretically; $\$2,310 \times 9$ patients = \$20,790), and that of 19 patients in the control group was \$60,814 (theoretically; $\$2,310 \times 19$ patients = \$43,890). As a result, \$42,444 were saved in wound care in the study group (Table VI). The triclosan-coated polyglactin 910 antimicrobial sutures, however, cost \$10.80 more than the equivalent nonantimicrobial sutures, so the material costs for the 206 patients in the study group were \$2,225 more than those in the control group ($\$10.80 \times 206$ patients). In summary, the actual savings using triclosan-coated sutures was at least \$40,219 (\$42,444 to \$2,225) in this study period.

Summary of wound infections in 28 patients. Table VII shows the details of the 28 infected cases. Of the cases, 14 were laparoscopic surgeries and only 3 cases had stoma. The most common infections were caused by *Enterococcus* species (12 of 28 cases), and the second most common infections were caused by *Bacteroides* species (8 of 28 cases). No differences were found between the study groups.

DISCUSSION

The above results indicate that the incidence of wound infection was reduced when triclosan-coated sutures were used for abdominal wound closure after colorectal surgery. To the best of the authors' knowledge, this trial is the first time that the effect of antimicrobial-coated sutures for abdominal closure has been evaluated by a prospective randomized trial in a larger cohort of colorectal surgery; other studies in the past included a smaller cohort. Retrospective studies of surgical-site infections are less reliable because data were collected from chart reviews, including operation reports, nurses' wound reports, wound documentations, and reports from databases of complications. Prospective studies ensure that criteria for the appearance of the incision are explicitly stated before the study starts and that all observers have been trained.¹⁸

Several studies have shown the efficacy of triclosan-coated polyglactin 910 antimicrobial

Table I. Demographic data of patients

Parameter	Study group (n = 206)	Control group (n = 204)	P value
Age (years)	69.4 ± 11.3	70.2 ± 11.1	.44
Gender			
Male	130	112	.09
Female	76	92	
Renal impairment	2	2	.99
Diabetes mellitus	41	31	.21
Smoker	81	79	.74
COPD	10	15	.29
Steroid use	1	3	.31
Past history of abdominal surgery	45	43	.85
BMI (kg/m ²)	23.2 ± 3.6	23.4 ± 3.8	.61
Serum albumin (g/dL)	3.46 ± 0.57	3.67 ± 0.55	.66
Lymphocyte (%)	27.3 ± 8.3	27.6 ± 9.9	.67
FBS (units)	120.9 ± 42.1	116.5 ± 33.9	.26
% Vital capacity	105.9 ± 20.8	106.3 ± 18.8	.42
% FEV1.0	77.1 ± 12.1	76.7 ± 10.2	.39
ASA class			
1	40	46	
2	148	142	
3	18	14	
4	0	2	
Wound classification			
Clean	0	0	
Clean contaminated	205	203	
Contaminated	1	1	
Dirty	0	0	

Data are shown as mean ± standard deviation or number of patients.

ASA, American Society of Anesthesiology; BMI, body mass index; COPD, chronic obstructive pulmonary disease; FBS, fasting blood sugar; %FEV1.0, percent predicted forced expiratory volume in 1 second.

Table II. Perioperative status of patients

Parameter	Study group (n = 206)	Control group (n = 204)	P value
Operation time (min)	238 ± 93	230 ± 88	.36
Blood loss (mL)	267 ± 536	237 ± 375	.50
Blood transfusion (mL)	89 ± 343	66 ± 231	.43
Lowest temperature during anesthesia (C°)	35.9 ± 0.53	35.9 ± 0.59	.95
Laparoscopic surgery	119	108	.33
Open surgery	87	96	
Stoma (+)	31	34	.65
Stoma (−)	175	170	
Operative procedure			
Right colectomy	61	61	
Transverse colectomy	13	11	
Left colectomy	11	9	
Sigmoidectomy	49	48	
Low anterior resection	41	41	
Abdominoperineal resection	21	23	
Total colectomy	1	2	
Simple colostomy	9	9	

Data are shown as mean ± SD or number of patients.

sutures (Vicryl* Plus) in decreasing the incidence of surgical-site infections.¹⁴⁻²² Of them, 3 studies included colorectal surgeries, and only 2 studies

were prospective randomized trials.^{15,18,19} Galal and El-Hindawy reported that triclosan-coated polyglactin sutures decreased postoperative

Table III. Incidence of wound infections and postoperative hospital stay

Parameters	Study group (n = 206)	Control group (n = 204)	P value
Wound infections	9 (4.3%)	19 (9.3%)	.047
Organ space SSIs	5 (2.4%)	4 (2.0%)	.74
Postoperative hospital stay(days)*	11 (6–79)	11.5 (6–93)	.08
Postoperative hospital stay(days)†	15.2 ± 11.6	15.6 ± 10.4	.71

*Median (range).

†Mean.

SSIs, Surgical site infections.

Table IV. Laparoscopic vs open approach

Parameters	Laparoscopic (n = 227)	Open (n = 183)	P value
Wound infection (%)	12 (5.3%)	16 (8.7%)	.16

Table V. Incidence of wound infections in laparoscopic and open approaches

Parameters	Study group	Control group	P value
Laparoscopic surgery	5/119 (4.2%)	7/108 (6.5%)	.43
Open surgery	4/87 (4.6%)	12/96 (12.3%)	.061

Table VI. Additional cost of wound infection

	Cost (US dollars)
Cost per patient (n = 28)*	\$2,310 (\$0–\$15,600)
Cost for the entire group†	
Control group (n = 19)	\$60,814
Study group (n = 9)	\$18,370
Cost savings in study group	\$42,444

*Median (range).

†Total cost of all wound-infected patients in each group.

surgical-site infections and had an impact on saving health care resources in a prospective randomized trial, but their trial included only 65 gastrointestinal patients of 450 general surgeries.¹⁸ The other prospective randomized trial showed that triclosan-coated polyglactin sutures decreased postoperative wound complications and length of hospital stay and were associated with a more rapid return of inflammatory markers to normal in 184 patients with colorectal cancer.¹⁹ The previous 2 studies entailed a smaller number of patients with a high rate of infection in the control group (13% to 15%).^{18,19}

In the current study, the data clearly show the efficacy of triclosan-coated polyglactin 910 antimicrobial sutures in colorectal surgery. The

risk factors influencing wound infections are comparable in the 2 groups (Tables I and II). Wound infections occurred in 9 of 206 patients (4.3%) in the study group versus 19 of 204 (9.3%) in the control group. The results in the study group are comparable to those in the other studies, whereas the incidence in the control group is lower compared with the previous studies.^{15,18,19}

In 2 studies, it has been shown that triclosan-coated polyglactin sutures decrease postoperative length of hospital stay^{18,19}; however, this study did not demonstrate the same finding (Table III). One of the reasons was that the wound infection rate in the control group was low, so the effect was small in comparison to the reduction in the total length of hospital stay in the study group. Second, 71% of the patients with wound infections were discharged after the same length of time of hospital stay as the noninfected patients, and the infected wounds were managed in the outpatient clinic.

Although the triclosan-coated polyglactin suture is more expensive, it may be more cost-effective for health care resources in the long term. The additional cost per patient of using triclosan-coated polyglactin suture is about \$10.80; therefore, the total additional cost for all 200 patients in 1 year is \$2,160. The median additional cost of wound-infection management is \$2,310 per patient. The annual cost of the antimicrobial-coated sutures, therefore, roughly corresponds with the cost of treating and managing 1 patient's wound infection. Hence, if 0.5% (1 in 200 patients) of wound infections are prevented by using triclosan-coated polyglactin sutures in a year, it will be more cost-effective for health care resources in the long term.

The above results also show that the laparoscopic approach is not associated with SSIs (Table IV). Several studies have shown that the laparoscopic approach is independently associated with reduced SSIs when compared with the open approach after colorectal surgery.^{26,27} Kiran et al showed that the wound infection rate was 7.6% vs

Table VII. Summary of wound infections in 28 patients

Case no	Suture	Wound classification*	Operative procedure	Causative organism
1	Control	II	Sigmoidectomy	<i>Enterococcus faecalis</i> , <i>Enterobacter cloacae</i> , <i>Bacteroides fragilis</i>
2	Control	II	Low anterior resection	<i>Enterococcus faecalis</i> , <i>Enterobacter cloacae</i>
3	Control	II	Laparoscopic right colectomy	<i>Enterococcus faecalis</i>
4	Control	II	Transverse colectomy	<i>Enterococcus faecalis</i>
5	Control	III	Sigmoidectomy	<i>Enterococcus fecium</i>
6	Control	II	Sigmoidectomy	<i>Enterococcus</i> sp.
7	Control	II	Laparoscopic right colectomy	<i>Enterobacter cloacae</i>
8	Control	II	Sigmoidectomy	<i>Bacteroides ovatus</i>
9	Control	II	Laparoscopic transverse colectomy	<i>Bacteroides fragilis</i>
10	Control	II	Laparoscopic sigmoidectomy	<i>Bacteroides</i> sp.
11	Control	II	Laparoscopic sigmoidectomy	<i>Pseudomonas aeruginosa</i> , <i>Bacteroides thetaiotaomicron</i>
12	Control	II	Sigmoidectomy	<i>Pseudomonas aeruginosa</i>
13	Control	II	Laparoscopic right colectomy	Methicillin-resistant <i>Staphylococcus aureus</i>
14	Control	II	Right colectomy	No data
15	Control	II	Laparoscopic right colectomy	No data
16	Control	II	Laparoscopic right colectomy	No data
17	Control	II	Transverse colectomy	No data
18	Control	II	Sigmoidectomy	No data
19	Control	II	Laparoscopic sigmoidectomy	No data
20	Study	II	Laparoscopic right colectomy	<i>Enterococcus faecalis</i> , <i>Bacteroides</i> sp.
21	Study	II	Abdominoperineal resection	<i>Enterococcus faecalis</i> , <i>Bacteroides fragilis</i>
22	Study	II	Abdominoperineal resection	<i>Enterococcus faecalis</i> , <i>Staphylococcus aureus</i>
23	Study	II	Abdominoperineal resection	<i>Enterococcus faecalis</i>
24	Study	II	Laparoscopic right colectomy	<i>Enterococcus</i> sp., <i>Enterobacter cloacae</i>
25	Study	II	Right colectomy	<i>Bacteroides</i> sp., <i>Staphylococcus epidermidis</i>
26	Study	II	Laparoscopic right colectomy	<i>Peptostreptococcus magnus</i>
27	Study	II	Laparoscopic sigmoidectomy	No data
28	Study	II	Laparoscopic low anterior resection	No data

*II, clean contaminated wound; III, contaminated wound.

12.7% in the LAP and open groups, respectively, according to the American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database; however, this study has a potential selection bias in that patients who undergo LAP surgery tend to have a significantly lower predicted risk for postoperative complications.²⁷ A literature search showed that 12 cases of patients' returning to the clinic and showing wound infection have been found.²⁸⁻³⁹ Although 2 of the trials showed a significantly lower incidence of SSIs after laparoscopic surgery compared with open surgery, the other 10 trials showed no difference. This trial's results show that the laparoscopic approach does not affect the rate of wound infections statistically (Table IV); however, the control group in open surgery had a higher wound infection rate, 12.3% (Table V), which suggests that the open surgery can potentially increase the risk for wound infections. A larger scale study of the selected group

should be conducted in the higher risk population of patients undergoing colorectal operations.

In this study, triclosan-coated polyglactin sutures reduced the incidence of wound infections and the cost of colorectal surgery; however, larger multicenter studies need to be conducted to provide more evidence.⁴⁰

The authors thank Dr Aya Kamei, Dr Youhei Hashimoto, Dr Tomohiro Kitada, Dr Kiyotaka Imamura, Dr Naoya Okada, Dr Yoshihide Nanno, and Dr Mayu Shimaguci for their support in this study. Also, we thank the health care information managers and medical clerks who have participated in this study for collecting the data on patients and Dr Christine Kwan for help in preparing the English manuscript.

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